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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,757	04/20/2006	Heike Sederoff	JIB-1571	9030

8076 7590 02/09/2011

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,757	SEDEROFF ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2010 and 30 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *17-19* is/are withdrawn from consideration.

5)☒ Claim(s) *11 and 13-16* is/are allowed.

6)☒ Claim(s) *1,2 and 4-10* is/are rejected.

7)☒ Claim(s) *3 and 12* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 March 2010* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: STIC Sequence Listing Error Report.

1. Applicant's election with traverse of the invention of Group I, claims 1-16, in the reply filed on May 6, 2009 is acknowledged. The traversal is on the ground(s) that the inventions relate to a single inventive concept, namely related peptides that block actin depolymerization through an F-actin-related mechanism. This is not found persuasive because the invention of Group II is not drawn to peptides, but rather is drawn to polynucleotides. Peptides and polynucleotides do not have a common property or activity, and do not share any significant structural elements. Note that multiple claimed products do not necessarily possess unity of invention. See 37 CFR 1.475(c) and (d).

The requirement is still deemed proper and is therefore made FINAL.

Claims 17-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on May 6, 2009.

In their response filed March 30, 2010, Applicants provide additional arguments traversing the restriction requirement. The examiner maintains his position that peptides and polynucleotides do not have a common property or activity, and do not share any significant structural elements. Applicants are invited to identify a single significant common property, activity, or structural element between peptides and polynucleotides if they disagree with this statement. While the examiner agrees that polynucleotides encode for the claimed peptides, this property of polynucleotides is not possessed by peptides. It is clear and obvious that a burdensome search is required to search both peptides and polynucleotides - because they are completely different compounds, completely different searches are required. The fact that claim

17 refers to claim 5 does not make claim 17 a dependent claim in accordance with PCT Rule 6.4. Claim 17 is not a dependent claim in accordance with PCT Rule 6.4, because it does not contain all of the features of claim 5. See MPEP 1850 at page 1800-99, column 2, second full paragraph (Rev. 7, July 2008). For example, claim 5 requires an isolated polypeptide, whereas claim 17 requires a polynucleotide. Accordingly, it is permissible to find lack of unity of invention between instant claims 5 and 17. Further, the anticipatory reference applied in the prior art rejection below is evidence that the invention as claimed lacks a special technical feature in common and therefore lacks unity of invention.

This application contains claims 17-19 drawn to an invention nonelected with traverse in the reply filed on May 6, 2009. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

Applicant's election of the species SEQ ID NO:12 in the reply filed on August 13, 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the election of species requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In their response filed March 30, 2010, page 12, last paragraph, Applicants contend that they did specifically point out the errors in the restriction, and thus the election should not be considered as having been made without traverse. The examiner has treated Applicants' election of the invention of Group I, in response to the restriction requirement, as being with traverse. However, Applicants' election of the species SEQ ID NO:12, in response to the election of species requirement, was made without distinctly and specifically pointing out the supposed errors in the election of species requirement. Accordingly, Applicants' species election has been

treated as having been made without traverse. The examiner has corrected the form paragraph in order to clarify this issue.

2. The replacement sheets of drawings and claim amendments filed March 30, 2010 have been entered. The specification amendments filed December 1, 2010 have been entered.

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reasons:

SEQ ID NO:25, as set forth in the amended Table 1 filed on December 1, 2010, is not the same as SEQ ID NO:25 as defined in the Sequence Listing filed December 1, 2010. Note that the former comprises 19 residues, whereas the latter comprises 20 residues.

The consensus sequence as defined in the Sequence Listing filed December 1, 2010, SEQ ID NO:25, does not appear to coincide with the aligned SEQ ID NOS:1-8 and 19-21 as set forth in Table 1 of the specification. For example, position 5 can be I for SEQ ID NO:6, but this variation is not included in SEQ ID NO:25. Position 6 can be T for SEQ ID NOS:5 and 6 but not Y, contrary to SEQ ID NO:25 as defined in the Sequence Listing. The first-listed definition for position 9 in SEQ ID NO:25 should be removed from the Sequence Listing. The first-listed definition for position 16 should be removed from the Sequence Listing, because it has been superseded by the second-listed definition for position 16 and by the definitions for positions 17-20 of SEQ ID NO:25.

The Sequence Listing filed December 1, 2010 was not approved by STIC for the reasons set forth in the attached STIC Sequence Listing Error Report.

Applicant must provide a substitute computer readable form (CRF) copy of the Sequence Listing, a substitute paper copy of the Sequence Listing as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and include no new matter as required by 37 CFR 1.825(a) and (b).

4. The drawings filed March 30, 2010 are objected to because: The meaning of the three superscript "^{N}" in Figure 1A, SEQ ID NO:18, is not known, and does not appear to be explained in the specification. If these were intended to stand for asparagine residues, revision of the sequence listing will be necessary.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The disclosure is objected to because of the following informalities: In amended Table 1 filed on December 1, 2010, a second hyphen has been inserted between the position numbers for each of SEQ ID NOS:5-8. The significance of having two rather than one hyphen between the position numbers is not clear. SEQ ID NO:25, as set forth in the amended Table 1 filed on December 1, 2010, is not the same as SEQ ID NO:25 as defined in the Sequence Listing filed December 1, 2010. Note that the former comprises 19 residues, whereas the latter comprises 20 residues. It is believed that the consensus sequence in amended Table 1 should have another hyphen added to its C-terminus, so that the consensus sequence in amended Table 1 is 20 residues in length. Appropriate correction is required.

6. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in the claim for the phrase "said compound" at claim 10, line 17.

7. Claims 3, 10, and 12 are objected to because of the following informalities: At claim 3, line 1, "A peptide" should be changed to "An isolated" so as to be consistent with the terminology used in amended claim 1. SEQ ID NOS must be inserted after all amino acid sequences subject to the sequence disclosure rules. See 37 CFR 1.821(d). Such a sequence is present in claim 10. At claim 12, line 11, "X2" should be changed to "X_2". Appropriate correction is required.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 1, 2, and 4-10 are rejected under 35 U.S.C. 102(a) and/or (e) as being anticipated by Liu et al (U.S. Patent Application Publication 2003/0034888). Liu et al teach a polypeptide identified as SEQ ID NO:54668 and having the following sequence:

```
SEQ ID NO 54688
LENGTH: 97
TYPE: PRT
ORGANISM: Glycine max
FEATURE:
OTHER INFORMATION: Clone ID: 700832792_FLI.pep
SEQUENCE: 54688
    Val Phe Gly Thr Glu His Ser His Ile Leu Arg Val Pro Phe Arg Thr
      1               5                  10                  15
    Glu Lys Gly Ile Val Arg Lys Trp Ile Ser Arg Phe Glu Val Trp Pro
                 20                  25                  30
    Tyr Leu Glu Thr Tyr Thr Glu Asp Val Ala His Glu Leu Ala Lys Glu
             35                  40                  45
    Leu Gln Gly Lys Pro Asp Leu Ile Val Gly Asn Tyr Ser Asp Gly Asn
         50                  55                  60
    Ile Val Ala Ser Leu Leu Ala His Lys Leu Gly Val Thr Gln Cys Thr
     65                  70                  75                  80
    Ile Ala His Ala Leu Glu Lys Thr Lys Tyr Pro Glu Ser Asp Ile Tyr
                     85                  90                  95
    Trp
```

Residues 19-34 of Liu et al's polypeptide correspond to Applicants' SEQ ID NO:12, and residues 26-31 correspond to Applicants' SEQ ID NO:22. In view of the similarity in amino acid sequence between Liu et al's polypeptide and Applicants' claimed peptide, inherently Liu et al's polypeptide will bundle actin and inhibit actin depolymerization to the same extent claimed by Applicants. Sufficient evidence of similarity is deemed to be present between Liu et al's polypeptide and Applicants' claimed peptides to shift the burden to Applicants to provide evidence that the claimed peptides are unobviously different than Liu et al's polypeptide.

10. Applicant's arguments filed March 30, 2010 and December 1, 2010 have been fully considered but they are not persuasive.

The objection to Figure 1A, contained in the Replacement Sheets filed March 30, 2010, because of the presence of the three superscripts "^{N}" in SEQ ID NO:18, is maintained. Applicants contend that the superscripts are intended to represent amine bonds present in peptides. However, a peptide backbone is typically comprised of amide bonds rather than amine bonds. Further, the amine group which is present at the N-terminus of the peptide is not bonded, via an amine or amide or any other type of bond, to any other group (with the obvious exception of the alpha carbon atom which is necessarily present in the arginine residue). The glutamic acid residue at position 7 of the peptide does not comprise any amine group available for bonding to the aspartic acid residue at position 8. Clarification of the drawing terminology is still required.

The anticipation rejection based upon Liu et al (U.S. Patent Application Publication 2003/0034888) is maintained (with the exception that amended claim 3 is no longer anticipated by the reference). Liu et al teach a polypeptide which meets all of the chemical structural requirements specified in the rejected claims. When a prior art product is known to possess all of the chemical structural requirements recited in a claim, it is permissible to assume, prima facie, that the prior art product also possess all of the properties and functions specified in the claim. Applicants have not rebutted this assumption by the submission of evidence showing that the prior art product does not actually possess the properties and functions specified in the claims. Admittedly, the polypeptide of Liu has not been shown by the examiner to possess the properties and functions specified in the rejected claims - this is the essential nature of an inherency rejection, and a well-recognized result of the fact that the Patent Office does not have the facilities necessary to test prior art compounds for their properties and functions. Unless the Winter et al article (FEBS Lett., Vol. 430, pages 205-208) actually tests the polypeptide of Liu et

al, it is not seen how the Winter et al article can be relied upon to show that the polypeptide of Liu et al does not actually possess the properties and functions specified in the claims. Finally, Applicants' assumption that amino acid residues in the center of a polypeptide sequence are necessarily unexposed to the polypeptide's external environment is unsupported. Whether or not particular residues of a polypeptide are exposed to an external environment is dependent upon the exact three-dimensional folding of that polypeptide in a particular external environment. Applicants have not submitted any evidence establishing the conformation of the polypeptide of Liu et al.

In response to Applicants' query, page 16 of the amendment filed March 30, 2010, second full paragraph, claims 11-16 were rejected under 35 U.S.C. 101 in the Office action mailed September 29, 2009. This rejection was overcome by the amendment to these claims filed March 30, 2010. There was no prior art rejection of these claims.

11. Claims 11 and 13-16 are allowed.

Claim 3 would be allowable if rewritten to overcome the claim objection set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claim 12 would be allowable if rewritten or amended to overcome the claim objection set forth in this Office action.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
February 9, 2011